K080780
Page 1 of 2

510(k) Summary
Epitek Anchorage™ Scope

APPLICANT:

JUL 30 2008

Epitek, Inc.
4801 W. 81st St., Suite 105
Bloomington, MN 55437 USA

Contact Person: Werner Hampl
Telephone: (952) 230-9886
e-mail: whampl@epitekinc.com
Date Prepared: March 17, 2008

DEVICE:

Proprietary Name: Anchorage Scope
Common/Usual Name: Endoscope
Classification: Class II;
21 CFR 876.1500;
Endoscope and accessories;
Product Code: GCJ

PREDICATE DEVICE:

The subject device is substantially equivalent (i.e., has the same intended use and technological characteristics) to the Flexible Fiber Optic Endoscope and Coupler (K991377) from OmniSonics Medical Technologies.

DEVICE DESCRIPTION:

The Anchorage™ Scope is a flexible fiber optic endoscope provided as a sterile single use device. The endoscope is used to visualize body cavities, organs, canals, and tissues. The Anchorage Scope is introduced through natural body cavities or surgical incisions through introducers or trocars, catheters, sheaths or other devices with lumens having an inside diameter greater than the outside diameter of the endoscope.

INDICATIONS FOR USE:

The Anchorage™ Scope is a flexible fiber optic endoscope intended for the

visualization of body cavities, organs, canals, and tissues. The Anchorage Scope is designed to be introduced through natural body cavities or surgical incisions through introducers, needles or trocars, catheters, sheaths or other devices with lumens having an inside diameter larger than the outside diameter of the endoscope. The Anchorage Scope is indicated for the following applications:

Ureteroscopy
Bronchoscopy
Thoracoscopy
Nasopharyngoscopy/Sinuscopy
General laparascopy
Urology
Gynecology

TEST RESULTS:

Results of the in-vitro testing, biocompatibility testing, and conformance to consensus and voluntary standards conducted prior to introduction into commerce demonstrate that the Anchorage Scope is substantially equivalent to the specified predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 30 2008

Mr. Werner H. Hampl
VP Operations & RA/QA
Epitek, Incorporated
4801 West 81st Street, Suite 105
BLOOMINGTON MN 55437-1111

Re: K080780
Trade/Device Name: Ancorage™ Scope Model 000003
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBO
Dated: July 20, 2008
Received: July 22, 2008

Dear Mr. Hampl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080780

Device Name: Anchorage™ Scope

Indications for Use:

The Anchorage™ Scope is a flexible fiber optic endoscope intended for the visualization of body cavities, organs, canals, and tissues. The Anchorage Scope is designed to be introduced through natural body cavities or surgical incisions through introducers, needles or trocars, catheters, sheaths or other devices with lumens having an inside diameter larger than the outside diameter of the endoscope. The Anchorage Scope is indicated for the following applications:

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General laparascopy
Urology
Gynecology

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K080780